DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 27, 2014

RTI Surgical Incorporated
Ms. Kristina Hall
Manager, Regulatory Affairs Submissions
11621 Research Circle
Alachua, Florida 32615

Re: K142070
Trade/Device Name: Fortiva™ porcine dermis, Tutoplast® porcine dermis
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM, OXF
Dated: July 29, 2014
Received: July 30, 2014

Dear Ms. Hall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

004 Indications for Use

510(k) Number (if known): K142070

Device Names: Fortiva™ porcine dermis
Tutoplast® porcine dermis

Indications for Use:

The device is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. Indications for use include the repair of hernias and /or body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome. The device is intended for reinforcement of soft tissues in plastic and reconstructive surgery.

The device is intended for single patient use only.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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005 510(k) Summary

Date: July 28, 2014

Submitted By: Kristina Hall
Manager, Regulatory Affairs Submissions
RTI Surgical, Inc.
11621 Research Circle
Alachua, FL 32615
Tel: 386-418-8888
Fax: 386-418-1627

Trade Name:
Fortiva™ porcine dermis, Tutoplast® porcine dermis

Classification Name and Code:
Mesh, surgical (21 CFR 878.3300, product code FTM)

Substantial Equivalence:
The proposed device is substantially equivalent to the predicate device Fortiva™ porcine dermis and Tutoplast® porcine dermis (K123356) in intended use, material, design, function and processing.

Description:
The proposed device is an implantable surgical mesh comprised of non-crosslinked porcine dermis that has been processed, terminally sterilized and is stored hydrated and ready to use. The proposed device is designed to perform as a scaffold that allows for neovascularization and permits replacement of the device with host tissue. The device in its unopened, undamaged package is sterile.

Indications for Use:
The device is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. Indications for use include the repair of hernias and /or body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome. The device is intended for reinforcement of soft tissues in plastic and reconstructive surgery.

The device is intended for single patient use only.

Summary of Technological Characteristics:
This device is comprised of non-crosslinked porcine dermis that has been processed, terminally sterilized and stored hydrated and ready to use. The device has the same technological characteristics as the predicate device in material, design, function, and processing as listed in the table below:

Characteristic	Proposed Device	Predicate Device (K123356)
Intended Use	Surgical mesh scaffold to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes.	
Material	Porcine Dermis	
Design	Terminally sterilized sheets in various sizes	
Function	Scaffold for soft tissue repair	
Processing	Proprietary tissue sterilization process	
Chemical composition	Not applicable to these devices	
Energy Source	Not applicable to these devices	

Performance Data Supporting Substantial Equivalence Determination:
The proposed device is equivalent to the predicate device in intended use, material, design, function, and processing. The biomechanical properties of the proposed and predicate devices were equivalent for the evaluated series of *in vitro* tests. Unimplanted tensile maximum load, burst strength and suture pullout strength were equivalent for the proposed and predicate devices.

The ability of the manufacturing process to inactivate model viruses was evaluated using porcine dermis at the stage in the chemical processing applicable to the chemical being evaluated. The results demonstrate the ability of the process to inactivate viruses with a wide range of characteristics (enveloped and non-enveloped, RNA and DNA, low resistance and high resistance) when used to process porcine dermis for the proposed device.

Pyrogenicity of the device was evaluated using the rabbit pyrogen test on the final sterilized device. The device did not elicit a response. All device lots will be tested to ensure the endotoxin level is <20 EU per device.

The device passed all applicable FDA Blue Book Memorandum G95-1 and ISO 10993-1 testing for the biological evaluation of medical devices. The structural and functional properties of the proposed and predicate devices were equivalent for the evaluated implantation study. Maximum tensile strength at the graft-host interface, burst strength, clinical and gross pathology, and the local effects of implantation were assessed and results were equivalent for the proposed and predicate devices. Results from *in vitro* and animal studies demonstrate that the proposed device is biocompatible, and as safe and effective as the predicate for use as a scaffold to repair soft tissue deficiencies.